DATA EVALUATION RECORD

- 1. <u>CHEMICAL</u>: Oxine Copper (Copper 8-Quinolinolate). Shaughnessey Number: 024002.
- 2. TEST MATERIAL: Ro 17-0099/000; Copper 8-Quinolinolate; bis-(8-quinolinolato)-copper; Batch No. 8293/3; 99.5% purity; a dark green/yellow powder.
- 3. <u>STUDY TYPE</u>: 71-1A. Avian Single Dose Oral LD₅₀ Test. Species Tested: Mallard duck (*Anas platyrhynchos*).
- 4. CITATION: Hakin, B., M.H. Rodgers and I. Grützner. 1991.
 Ro 17-0099/000 (Copper 8-Quinolinolate): Acute Oral Toxicity to Mallard Duck. Study performed by Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England, and RCC UMWELTCHEMIE AG, Itingen, Switzerland. Laboratory Study No. HLR 185-901733/RCC 284264. Submitted by La Quinoleine et ses dérivés, S.A. EPA MRID No. 429271-02.
- 5. REVIEWED BY:

Michael L. Whitten, M.S. Wildlife Toxicologist KBN Engineering and Applied Sciences, Inc.

6. APPROVED BY:

Mark A. Mossler, M.S. Associate Scientist KBN Engineering and Applied Sciences, Inc.

James J. Goodyear, Ph.D. Project Officer, EEB/EFED USEPA

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CONCLUSIONS: This study is scientifically sound, and meets the guideline requirements for an avian oral LD₅₀ test. With an LD₅₀ of greater than 2000 mg/kg (nominal concentration), the test material is classified as practically non-toxic to the mallard duck. The NOEL was

2000 mg/kg.

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- 8. RECOMMENDATIONS: N/A.
- 9. BACKGROUND:
- 10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Mallard ducks (Anas platyrhynchos) were obtained from a commercial supplier in Kent, England, and were phenotypically indistinguishable from wild birds. The birds were acclimated to the facilities for 14 days, and were approximately 15 months of age at test initiation.
- B. Test System: Birds were housed indoors in pens constructed of galvanized steel with wire mesh floors. Artificial lights provided 7 hours of light per day. The average minimum and maximum temperatures during the study were 19 ± 0.7°C and 22 ± 0.7°C, respectively, with a mean relative humidity of 68 ± 8.1%.
- C. <u>Dosage</u>: Fourteen-day single dose oral LD₅₀ test. Dosages selected for the study were 0, 500, 1000, and 2000 milligrams of Ro 17-0099/000 per kilogram of body weight (mg/kg).
- Design: The birds were assigned to treatment groups based on bodyweight, with the goal of similar mean bodyweights in each group. Groups of ten birds (five males and five females) were assigned to each treatment and control group. Each dosage group was assigned two pens in which the birds were segregated by sex. Birds were fed HRC layer diet. Food and water were supplied ad libitum during acclimation and during the test, except during the 18-hour period immediately prior to dosing, when food was withheld.

The test substance was dispersed in corn oil. Dosages were administered by oral intubation using a syringe and plastic catheter. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received a corresponding volume (5 ml/kg) of corn oil. Samples of the dosing solutions were collected to verify test concentrations, and were analyzed using high performance liquid chromatography.

All birds were observed daily for mortalities, signs of toxicity, and abnormal behavior. The birds were

individually weighed on days -14, -7, 0, 7, and 14. Group food consumption was determined for days -14 to -8, -7 to -1, 1 to 7, and 8 to 14.

Macroscopic post mortem examinations were conducted on ten birds from the highest dosage group at study termination.

- E. Statistics: Since no birds died during the study, the LD₅₀ and 95% confidence interval were not statistically calculated.
- 12. REPORTED RESULTS: Analyses of dosing solutions showed that measured concentrations of test material were within the range of 96.1 to 101.3% of nominal values.

There were no mortalities in the control group, nor in any treatment group. All birds in the control and treatment groups were normal in appearance and behavior throughout the study.

There was no evidence of any treatment-related effects on bodyweight or food consumption at any treatment level (Tables 1 and 2, attached).

No abnormalities were noted at necropsy.

13. <u>STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:</u>
The oral LD₅₀ was greater than 2000 mg/kg.

The report confained statements certifying that the study was inspected by the laboratory's Quality Assurance department. The GLP statement was as follows: "The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160."

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. <u>Test Procedure</u>: The test procedures were in accordance with Subdivision E and SEP guidelines with the following exception:

The birds were not randomly assigned to groups.

Instead, the assignments were based on bodyweight, with the goal of similar mean bodyweights in each group.

B. <u>Statistical Analysis</u>: Since no birds died, no statistical analyses were conducted.

C. <u>Discussion/Results</u>: The birds were not randomly assigned to groups. Instead, the assignments were based on bodyweight, with the goal of similar mean bodyweights in each group. This method of assignment probably did not affect the outcome of the test. The registrant, however, should enact procedures in future tests that provide random assignments to groups.

Based on nominal concentrations, the LD_{50} was greater than 2000 mg/kg. This value classifies the test material as practically non-toxic to the mallard. The NOEL was 2000 mg/kg. The study is scientifically sound, and meets the guideline requirements for an avian oral LD_{50} test.

D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: N/A.
- (3) Repairability: N/A.
- 15. COMPLETION OF ONE-LINER: Yes; December 15, 1993.

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Ecological Effects Branch One-Liner Data Entry Form

Pesticide Use

Chemical DXine Copper shaughnessy No. 024002.

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LAB	HKC					LAB			,		
MRID/ CATEGORY	CORE					MRID/ CATEGORY					
STUDY/REVIEW DATES	(aq1/1493					STUDY/REVIEW DATES					
NOEL	2000 mg/kg					NOEL		±.,			
SLOPE	1/4					SLOPE					
LD ₅₀ (95%CL)	7-2000 ay					LC ₅₀ (95%CL)					
A A	99.5					& AI					
AVIAN ORAL TOX	A T	1	3.	4.	5.	AVIAN DIETARY SPECIES (AGE)	12	2.	3.	4.	Ď.

COMMENTS: